

UTAH STATE DEPARTMENT OF HEALTH

LAW

AND

RULES AND REGULATIONS PERTAINING

TO THE

TESTING OF NEWBORN INFANTS

FOR

PHENYLKETONURIA AND OTHER INBORN METABOLIC DISEASES

1965

ADOPTED BY

UTAH STATE BOARD OF HEALTH, JULY 21, 1965

UNDER AUTHORITY OF

26-17-21 AND 22

UTAH CODE ANNOTATED 1953

AS AMENDED

PKU LAW

UTAH CODE ANNOTATED 1953, AS AMENDED*

26-17-21. PKU tests of newborn infants Board of Health to establish rules and regulations.--The State Board of Health shall establish rules and regulations requiring each newborn infant to be tested for the presence of phenylketonuria (PKU) and other metabolic diseases which may result in mental retardation or brain damage and for which a preventive measure or treatment is available and for which a laboratory diagnostic test method had been found reliable.

26-17-22. Violations of rules and regulations Misdemeanor.-- Any violation of the rules and regulations promulgated under this act by the Board of Health shall be a misdemeanor.

*Enacted by 1965 Legislature

July 21, 1965

RULES AND REGULATIONS
TO PROVIDE
TESTING OF NEWBORN INFANTS
FOR
PHENYLKETONURIA AND OTHER INBORN METABOLIC DISEASES

Pursuant to Sections 26-17-21 and 22, Utah code annotated 1953, as amended, rules and regulations pertaining to the testing of newborn infants for the presence of phenylketonuria (PKU) and other inborn metabolic diseases are hereby adopted by the Utah State Board of Health effective August 15, 1965.

Section I. DEFINITIONS--For the purpose of these rules and regulations, the following terms shall have the meaning indicated in this section unless a different meaning clearly appears from the context.

1. "Department" shall mean the Utah State Department of Health.
2. "PKU" shall mean phenylketonuria or phenylketonemia.
3. "Approved Test" shall mean tests approved by the Department for detection or diagnosis of PKU or other specified inborn metabolic diseases.
4. "Confirmatory Test" shall mean a quantitative blood test approved by the Department to be used in the further evaluation of any prior positive test.
5. "Approved Laboratory" shall mean a laboratory which has been approved by the Department for performing approved tests for the detection of PKU or other inborn metabolic diseases.
6. "Hospital" shall mean a Utah hospital which provides maternity services.
7. "A Negative PKU Test" shall mean a blood test that shows less than 4 mgs. of phenylalanine per 100 milliliters of blood when the specimen has been taken under conditions specified in these regulations.
8. "A Positive PKU Test" shall mean a blood test that shows 4 mgs. or more of phenylalanine per 100 milliliters of blood when the specimen has been taken under conditions specified in these regulations.

Section II. PROCEDURES

1. Every newborn child shall receive two approved tests for the detection of PKU: The first one after the infant has been on milk feedings for 24 hours or before discharge from the hospital, whichever occurs first, and the second one between 4 and 6 weeks of age.

2. Every hospital providing maternity services shall provide the necessary equipment, facilities, services and procedures for the taking of blood specimens for an approved test, for forwarding such specimens to an approved laboratory, for maintaining appropriate records and for transmitting all information and reports on the test results to the patient's physician of record and to the State Department of Health.

3. Every physician or other person responsible for signing the birth certificate of a newborn child shall take or arrange for the taking of the first blood specimen for an approved test, after the infant has been on milk feedings for 24 hours or before the infant's discharge from the hospital, whichever occurs first. Before the patient leaves the hospital the physician shall inform the parent(s) or other responsible person or agency of the legal requirement for a second approved test to be made when the infant is 4 to 6 weeks of age and advise how such tests may be obtained.

4. Every parent or legal guardian shall be responsible for obtaining for their newborn child the legally required approved tests.

Section III. LABORATORIES--APPROVED, TEST PROCEDURES AND REPORTING

1. Approval. Laboratories in Utah will be granted approval by the Department upon application, initially and thereafter upon review annually under the following conditions:

- a. The laboratory is supervised by a person who, by virtue of education, training, and experience, is deemed by the Department to be qualified for this responsibility.
- b. The laboratory agrees to participate and thereafter does participate in a technique evaluation study using "unknown" or reference specimens furnished by the Department. Results of such studies shall be considered by the Department in its approval of a laboratory.
- c. The volume of testing done by the laboratory shall be 20 or more tests per week.
- d. The laboratory shall comply with all applicable requirements of these regulations.
- e. Withdrawal of approval of a laboratory may occur at any time when in the discretion of the Department Director the approval conditions are not fulfilled. Prior to such action, the laboratory shall be warned of the contemplated action and allowed a reasonable time for the correction of the conditions which have caused the concern of the Department Director.

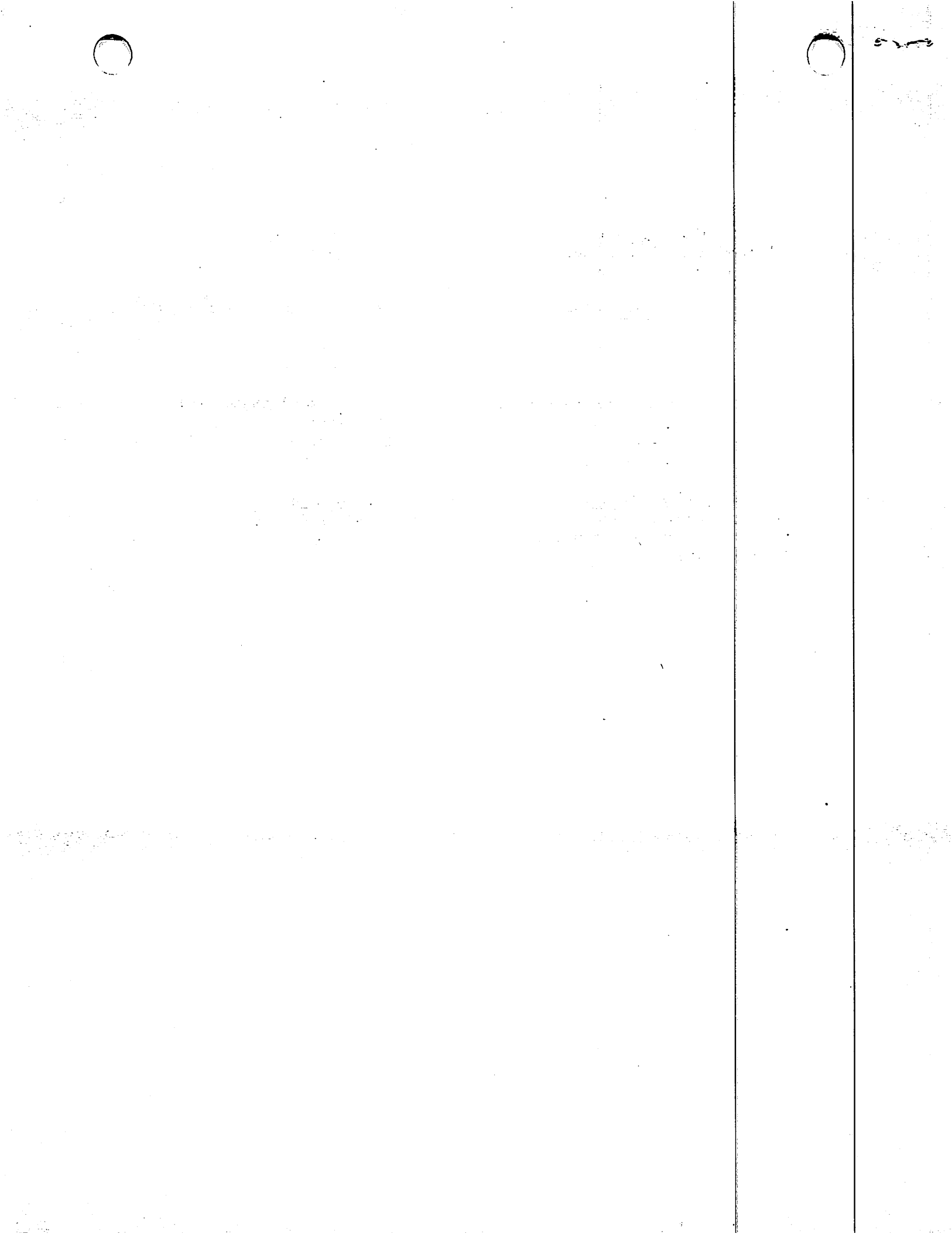
Such action would consist of written notification to the laboratory and the hospitals and physicians utilizing its services.

2. Testing Time. The approved test shall be performed by the laboratory at least once weekly and shall include all specimens received prior to the test day.

3. Reporting. The approved laboratory shall report as follows:

- a. Negative test reports shall be forwarded weekly to the hospital submitting the specimen and to the Department.
- b. Positive test reports shall be telephoned immediately to the attending physician of the affected infant and reported immediately by mail to the hospital in which the child was born and to the Department.

4. Notice of Approved Tests and Approved Laboratories. The Department shall issue and distribute periodically notices of approved tests and approved laboratories to physicians, hospitals and laboratories in the State.



UTAH STATE DEPARTMENT OF HEALTH

UTAH LABORATORIES PROVISIONALLY* APPROVED FOR PKU DETECTION

7-26-65

(Currently Restricted to Guthrie Inhibition Assay Method)

Salt Lake City

Cottonwood Hospital Laboratory

Holy Cross Hospital Laboratory

Latter-Day Saints Hospital Laboratory

St. Mark's Hospital Laboratory

University of Utah Medical Center Laboratory

Valley West Hospital Laboratory

Ogden


St. Benedict's Hospital Laboratory

Thomas D. Dee Memorial Hospital Laboratory

Provo

Utah Valley Hospital Laboratory

Signed


G. D. Carlyle Thompson, M.D.
Director of Public Health

- * Provisional approval is granted for a period of 90 days (10-26-65) and for the Guthrie Inhibition Assay Method to permit the immediate operation of the new law. As Utah laboratories formally meet the provision of the Rules and Regulations adopted by the State Board of Health on 7-21-65, approval will be given for those detection and confirmatory tests procedure covered by the laboratory application.

